

## **How can qualitative research enhance and strengthen randomised controlled trials undertaken with children and young people?**

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## **Evidence Based Nursing: Research Made Simple Series**

**Title: How can qualitative research enhance and strengthen randomised clinical trials undertaken with children and young people?**

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Health research aims to improve people's health by understanding the best ways to diagnose and treat conditions, and understand people's responses to health problems and health promotion initiatives. Quantitative research, and more specifically randomised controlled trials (RCTs), aims to establish if an intervention works, for example testing the effectiveness of a new drug, using statistical analysis. In contrast, qualitative research focuses on understanding a situation, for example people's experiences, perspectives and behaviours. Qualitative research can enhance RCTs by ensuring a more complete understanding of the factors that influence the acceptability of a new intervention and how it might be implemented in practice. A previous article in this series outlined how process evaluation embedded within RCTs can help understand how and why an intervention works.<sup>1</sup> While process evaluation is important, we will outline the reasons qualitative research can enhance the design and procedures associated with RCTs, and the interpretation of findings. We will outline the key features of RCTs and the underpinning principles of qualitative research before offering strategies that could be incorporated into RCTs to maximise the potential benefits to children and young people (CYP) and their families.

### **What is a randomised controlled trial?**

Quantitative research gathers numerical data using objective and highly structured data collection tools such as surveys / questionnaires and patient data such as observation and test results. Broadly, quantitative research is either: 1) Descriptive, such as prevalence studies where the characteristics of a

population are described (for example *how many young people have asthma*) or correlational studies that examine the relationship between variables (for example *how many young people who have asthma smoke*); or 2) Experimental, which aim to establish cause and effect relationships (for example *does smoking exacerbate asthma symptoms*). While the strength of quantitative research is to establish relationships between variables of interest in controlled environments, findings can be difficult to apply in everyday contexts. In addition, standardised collection of numerical data can result in the information gathered not reflecting outcomes important to patients.

RCTs are deemed the ‘gold standard’ research approach for establishing the effectiveness of a health intervention. Interventions are anything that can improve health or disease management and while typically thought of as drug therapies can include education programmes, changes to policy or the way care is delivered. What is important is that the impact of the change (outcomes) can be measured. An important feature of RCTs is that participants are randomly assigned to one of two groups, those who receive the intervention and those who do not (the control or comparison group).

An example of a nurse led RCT is a study that evaluated the effectiveness of the digital WeChat Mini Programme to improve disease management in children with asthma.<sup>2</sup> One group undertook the WeChat Mini Programme alongside usual care; the comparison group received usual care. The Childhood Asthma Control Test was used with both groups to assess the frequency of exacerbations, medication use and lung function. The study found that the WeChat Mini Programme improved the child’s asthma. However, as recognised by the researchers, some parents stated that due to time pressures they struggled to complete the data log thus decreasing their motivation to continue with the programme. Embedding a qualitative element within the RCT could have identified strategies to enhance parental engagement with the study.

### **What is qualitative research?**

Qualitative health research is useful for helping us to understand people’s behaviours in relation to managing their health and accessing services, and following health promotion initiatives to stay healthy. In addition, qualitative research can find out about patients experiences and what they think about health services, engaging with health professionals, and observe what happens in a practice setting. Unlike quantitative approaches, which focus on numerical data, qualitative approaches primarily use audio or video data, typically collected through interviews, focus groups and observation. Analysis of the information obtained should represent what has been said or observed and through interpretation a nuanced account of the topic is offered. Qualitative health research findings typically report people’s experiences and perspectives but may also offer an explanation as to how and why patients follow treatments, information and guidance, and explain how health interventions may or may not work.

An RCT that compared the addition of digital home monitoring (smart inhaler) for asthma management with usual care included qualitative interviews with mother and child dyads to explore their views of the smart inhalers.<sup>3</sup> The quantitative analysis found the addition of the smart inhaler improved the child's adherence to prescribed inhalers and medication. The qualitative analysis highlighted that both mothers and children perceived the smart inhaler was not user friendly. They were frustration with the technology including a short battery life and failures in downloading test results. In addition, while the smart inhaler was perceived as a useful adjunct to care participants did not want it to replace health professional support. This information would not have been obtained by solely using quantitative methods.

### **Why is incorporating qualitative research within RCT important?**

Few health research questions can be sufficiently understood through quantitative research alone. The example above highlights the value of combining qualitative and quantitative approaches to obtain a holistic understanding of the impact of the smart inhaler for the child and family.<sup>3</sup> However, qualitative approaches have typically been undervalued in health research. This in part resulted from the emergence of hierarchies of evidence during the 1990s; typically qualitative research approaches are ranked lower than quantitative approaches and more specifically RCTs.<sup>4</sup> Hierarchies of evidence can be overly simplistic and do not always consider the complexity of many healthcare interventions. In addition, evidence hierarchies may not be reflective of different profession or patient priorities or value the merit of different research designs.<sup>4,5</sup> Research involving multiple methods of data collection and analysis can offer a more complete understanding of a topic.

A limitation of RCTs is data collection is decided in advance of the study and only what can be quantified. Qualitative approaches are less restrictive and not limited to what can be quantified. Data collection can be adapted as new information comes to light once the researcher enters the research field. This is particularly important if CYP and families identify essential outcomes not previously considered. Embedding qualitative approaches within an RCT can ensure greater understanding of the context in which an intervention will be experienced including social, cultural and environmental factors. This adds context and relevance to the findings of the RCT. Researchers can work with CYP and their families to guide the RCT design, recruitment procedures, develop study information and consent forms, and appropriateness of data collection strategies. In addition, RCTs with an 'embedded' qualitative approach should include exploring CYPs' and their families' experiences of taking part in the study.

### **How can qualitative research methods be incorporated into RCTs?**

So far we have outlined the importance of embedding qualitative research within RCTs, yet there is little guidance on how best to combine qualitative designs within RCTs. In Table 1, we offer suggestions across each stage of the RCT.

**Table 1: Embedding qualitative research within RCTs**

RCT Stage	Examples of how to include qualitative approaches
Pre-trial	<p>Optimise RCT uptake and retention of participants by:</p> <ul style="list-style-type: none"> <li>- Stakeholder / patient engagement activities such as workshops to establish relevance of the research to CYP and families</li> <li>- Interviews and focus groups to explore CYP and families perspectives to inform the RCT protocol including what procedures would be tolerated</li> <li>- Establish a CYP or /and family steering group that can inform recruitment processes, obtaining and sustaining informed consent, and identifying meaningful patient outcomes</li> </ul>
During the RCT	<p>Optimise the delivery of the RCT, minimise recruitment drop out, and enhance the relevance of the findings to CYP and families can include:</p> <ul style="list-style-type: none"> <li>- Mini interviews, short feedback forms such as 'postcards' after each point of contact to identify any issues that might impact on the delivery of the trial</li> <li>- Provide on-going positive feedback, valuing CYP participation and time commitments</li> <li>- Review feedback with steering group members to identify possible solutions that will improve CYP experiences of participating in the RCT</li> <li>- Interviews and focus groups to understand CYP's experiences of the intervention including how it might work in 'real life'</li> <li>- Input from steering group to review findings and help decide key messages will enhance the quantitative findings</li> </ul>
Post trial	<p>Optimise dissemination of the findings and identify ways to improve the design of future RCTs</p> <ul style="list-style-type: none"> <li>- Include qualitative process evaluations to support the implementation of the interventions</li> <li>- Input from steering group to identify strategies such as social media to disseminate findings including to patient groups/ wider public</li> <li>- Interviews, focus groups or feedback 'postcards' to obtain feedback on the experiences of participating in the RCT</li> </ul>

In summary, qualitative methods are increasingly embedded within RCTs, particularly for complex interventions where the effectiveness of intervention is dependent on CYP and family behaviours. Qualitative research can contextualise and provide important insights into quantitative findings. We have suggested ways qualitative methods can be incorporated into RCTs.

## References

- <sup>1</sup>Bugge C. What is a process evaluation when used alongside a randomised controlled trial? *Evidence-Based Nursing* 2024 27; 45-47. <https://ebn.bmj.com/content/ebnurs/27/2/45.full.pdf>
- <sup>2</sup>Wu JM, Yang TH, Qin X, Liu D. Yan He. Effectiveness of specialist nurse-led WeChat mini program management for disease control in asthma: A randomized controlled study. *Journal of Pediatric Nursing* 2024; 79: e93-e99. <https://doi.org/10.1016/j.pedn.2024.10.004>
- <sup>3</sup>Lawrie L, et al. A qualitative process evaluation within a clinical trial that used healthcare technologies for children with asthma—insights and implications. *Plos one* 18.1 (2023): e0280086 <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0280086>
- <sup>4</sup>Vere J, Gibson B. Variation amongst hierarchies of evidence. *Journal of Evaluation in Clinical Practice* 2021; 27(3):624-630 <https://pubmed.ncbi.nlm.nih.gov/32364299/>
- <sup>5</sup>Hoogeboom TJ, Jette AM. Using Evidence Hierarchies to Find the Best Evidence: A Procrustean Bed? *Physical Therapy* 2021; 1: 101 (11), pzab235. <https://doi.org/10.1093/ptj/pzab235>